K093747
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Bard Medical Division
C. R. Bard Inc
8195 Industrial Blvd.
Covington GA 30014

BARD

MAY - 7 2010

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. SUBMITTER INFORMATION:

Submitter's Name:	C. R. Bard, Inc.
Address:	Bard Medical Division 8195 Industrial Blvd. Covington, GA 30014
Contact Person:	John Knorpp
Contact Person's Telephone Number:	770-784-6316
Contact Person's Fax:	770-385-4706
Summary Prepared On:	February 17, 2010

B. DEVICE NAME:

Trade Name(s):	Align® Urethral Support System Align® TO Urethral Support System
Common/Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Polymeric (21 CFR 878.3300, Product Code OTN

C. PREDICATE DEVICE NAME:

Trade Names:	Align® Urethral Support System Align® TO Urethral Support System K070073

D. DEVICE DESCRIPTION:

The Align® Urethral Support System and Align® TO Urethral Support System (Align® System) include a sterile, single use permanent implant that provides support for the urethra in female patients with stress urinary incontinence. The mesh consists of a knitted, open porosity, monofilament, polypropylene mesh strip, which is self-anchoring. The open porosity of the mesh design and large pore sizes allow for macrophage penetration and the creation of an inert scaffold for tissue ingrowth to create a permanent support for the urethra. The knitted polypropylene mesh is made from a small diameter fiber which creates a soft and pliable material.

The mesh sling is encased in a removable, protective sheath assembly. The sheath assembly consists of a PTFE tube with a Peel-Away tab that is used to separate the two sections of the sheath for removal of the sheath assembly after the implant has

been placed. At the ends of the sheath are flexible green polyurethane tubes to aid in placing the device and for easy visualization during cystoscopy. The sheath incorporates a stainless steel dilator that smoothes the transition from the green tubing to the protective sheath to aid in sheath removal. Push on polypropylene connectors at each end of the green tubes are used to connect the device to the introducers.

Because of the different surgical approaches that may be used to place the device, the same implant is offered in several kit configurations depending on the surgical approach (retropubic, suprapubic, or transobturator) to be used for placement of the mesh implant.

E. INTENDED USE:

The Align® System is indicated for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. There have been no changes to the intended use or indications for use.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

The subject device Align® System has the same design, materials and fundamental scientific technology as the predicate device (described above) with the exception of the dilator. The predicate device does not include a dilator. The subject device incorporates a stainless steel dilator that smoothes the transition from the green tubing to the protective sheath to aid in sheath removal.

G. NON-CLINICAL PERFORMANCE DATA SUMMARY:

The tests performed include dimensional, tensile strength and insertion force testing. A cadaver study was also performed to evaluate the ability of the sheath to easily glide through tissue during implantation and the ease of sheath removal. The results of these non-clinical tests demonstrate that the subject device met the predetermined acceptance criteria and performed as well or better than the predicate device and/or other legally marketed devices that incorporate a dilating feature (American Medical System's Monarc® Sling (K051530, K081613) and Boston Scientific's Obtryx® / Lynx® Sling (K081275)).

H. CLINICAL DATA SUMMARY:

Clinical data is not necessary to determine substantial equivalence.

I. CONCLUSION:

The results from the non-clinical performance data summarized above demonstrate that the Align System is as safe, as effective, and performs as well as or better than the predicate device and/or other legally marketed devices that incorporate a dilating feature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

C.R. Bard, Inc.
% Ms. Michelle Gudith
Bard Medical Division
8195 Industrial Boulevard
COVINGTON GA 30014

SEP 28 2012

Re: K093747
Trade/Device Name: Align® Urethral Support System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: April 8, 2010
Received: April 8, 2010

Dear Ms. Gudith:

This letter corrects our substantially equivalent letter of May 7, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1.4 Indications for Use Statement

510(k) Number (if known): _____

Device Name: Align® Urethral Support System

Indications for Use:

The Align® Urethral Support System is indicated for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093747